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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,804	06/20/2001	Lea Eisenbach	EISENBACH 3	6094

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,804	EISENBACH ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004 and 20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 16, 19, 21, 23, 44, 55-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16 and 55-57* is/are allowed.

6)☒ Claim(s) *1,19,21,23,44 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2004 has been entered. Claims 1, and 19 are amended. Claims 1, 16, 19, 21, 23, 44, 55-58 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Claim Objections, Withdrawn

The objection of claim 1 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 1, 19, 21, 23, 44, 45, 53, and 58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Following Are New Grounds of Rejection

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1, and 19 are both limited to SEQ ID NO:78 drawn to human Lactadherin (BA-46), therefore, claim 19 does not further limit the base claim.

Claim Rejections - 35 USC § 112

Claims 1, 19, 21, 23, 44, and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOs: 35-41, does not reasonably provide enablement for other peptides consisting of 9 or 10 contiguous amino acid residues in the sequence of SEQ ID NO:78. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification at Fig. 15-17 discloses that instant SEQ ID NOs:35, and 38 work best to promotes effective binding to a MHC class 1 type molecule so as to elicit a CTL response while BA46-8 shown at Fig. 16 does not work as well as other peptides form the instant SEQ ID NO:78, which is 387 amino acids in length. This means there are numerous in fact over 1,0000 different 9 or 10 amino acid residues could be generated using instant the SEQ ID NO:78. However, the specification does not disclose common structural attributes that promote effective binding to a MHC class 1 type molecule so as to elicit a CTL response. This indicates that one has to determine experimentally which one of the over 1,000 different peptides could work to promotes effective binding to a MHC class 1 type molecule so as to elicit a CTL response. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

US Pat. 5,840,839 (Nov. 24, 1998, cited in the Office action mailed on 3/13/2003) teach at column 19 that finding a peptide that binds to a MHC molecules and stimulates immune response is not a trivial matter. The '839 patent at column 19, lines 53 to 67 teaches that structure a T cell epitope that stimulates immune response in context of MHC molecules is unpredictable in the current state of art. The '839 patent at columns 19-20, and Table 1 teaches that the various candidate T cell epitopes selected based on theoretical binding motif of one class of MHC molecule, i.e. HLA-A31 do not work when they are experimentally tested as shown in Table 1. This suggests that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not.

Considering the unpredictable state of art, limited guidance, the broad scope of the claims, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

Claims 1, 19, 21, 23, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Guagler et al., (1994, J. Exp. Med. Vol. 179, pages 921-930).

Claims 1, 19, 23, and 44 are interpreted as drawn to an isolated peptide consisting of 9 or 10 amino acid residues made by a non-natural modification to a peptide consisting of 9 or 10 contiguous amino acids residues in the sequence of SEQ ID NO:78, wherein said isolated peptide promotes effective binding to a MHC class 1 type molecule so as to elicit a CTL response, wherein one of said modification is residue modification (claim 23), wherein the second and the C-terminal residues are neutral, hydrophobic, and aliphatic (44).

Guagler et al., teach an isolated peptide consisting of 9 or 10 amino acid residues made by a non-natural modification to a peptide consisting of 9 or 10 contiguous amino acids residues in the sequence of SEQ ID NO:78, i.e. "EVDPIGHLY" at Figure 6 (page 927), wherein said isolated peptide promotes effective binding to a MHC class 1 type molecule so as to elicit a CTL response. Since the claims do not limit how many of amino acids could be modified as long as a modification is present (note the claims construction of claim 1 as compared to claim 21), the instantly claimed isolated peptide consisting of 9 or 10 amino acid residues reads on the sequences shown at Fig. 6 or Fig 7 because 7 amino acids (meet the limitation "at least one non-

natural modification" in the instant claim 21, "residues modification" of amino acid residue #43 to 51 (EVRGDVFPS) of instant SEQ ID NO:78, for example, becomes "EVDPIGHLY" as shown in Fig. 3 of the art. As for claim 44, the 9-mer peptide sequences of Guagler et al., have the second and the C-terminal residues are neutral, hydrophobic, and aliphatic. "A" (alanine) in the second residue and "Y" (tyrosine) the end residue are neural, hydrophobic, and aliphatic. Since the specification does not define "neural, and "hydrophobic" amino acids, the Office broadly interprets that all of the standard 20 amino acids except those 5 charged residues (Lys, Arg, His, Asp, Glu) are encompassed by the limitation of "neutral, hydrophobic and aliphatic" in claim 44. Note at page 921, the sentence bridging left and right columns that HLA-A1 is a MHC class I molecule.

Thus, the instant claims 1, 19, 21, 23, and 44 read on the peptides sequences shown at Figs 6, and 7 of Guagler et al.

Allowable Subject Matter

Claims 16, and 55-57 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642